

3. RESPONSE/REMARKS

3.1 STATUS OF THE CLAIMS

Claims 1-59 were pending at the time of the Action.

Claims 2, 3, 5-13 and 43-57 have been withdrawn from consideration.

Claims 1, 4, 13, 14, 16, 25, 27, 30, 36 and 40 have been amended herein.

Claim 58 is indicated as allowable (the Action page 2, paragraph 4)

Claims 1, 4, 14-42 and 58-59 remain pending in the Application.

Applicants respectfully request reconsideration of the remarks herein, removal of all outstanding claim objections and rejections, and allowance of all pending claims.

3.2 APPLICANTS RENEW THEIR REQUEST FOR RECONSIDERATION UNDER

37 C. F. R. § 1.143

Pursuant to 37 C. F. R. § 1.143, which states in pertinent part:

“If the applicant disagrees with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving the reasons therefor. In requesting reconsideration the applicant must indicate a provisional election of one invention for prosecution, which invention shall be the one elected in the event the requirement becomes final. The requirement for restriction will be reconsidered on such a request. If the requirement is repeated and made final, the examiner will at the same time act on the claims to the invention elected.”

Applicants again request the Examiner’s Reconsideration of the restriction requirement/species election.

The practice set forth in 37 C. F. R. § 1.146, states that if an “application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the

claims to not more than *a reasonable number of species* before taking further action in the application.” (emphasis added).

In the instant Application, the Office has agreed to examiner only a *single* mRNA target sequence within the IFG-1R-encoding mRNA, and to permit Applicants to claim only a single ribozyme species that specifically cleaves the specific sequence. The plain language of this rule, however, is clear. If the intent of the Rule was to limit an Applicant to claiming only a single species within a genus of species in a single application, then the Rule would not state “a reasonable number of species” may be Examined – the Rule would state that Applicant must claim only ONE species and not “a reasonable number.” To that end, Applicants request the Examiner’s reconsideration of the finality of the species requirement in the instant Application.

3.3 APPLICANTS RENEW THEIR RIGHT TO PETITION UNDER 37 C. F. R. § 1.144

Since the Examiner has now made a final requirement for restriction, despite Applicants’ earlier arguments against the same, despite Applicants’ request for vacation of further restriction and imposition of species election, and despite Applicants’ formal request herein for Reconsideration, Applicants hereby give constructive notice of their right to Petition the final holding of restriction to the Group Director pursuant to 37 C. F. R. § 1.144. As provided by the Rule, Applicants currently defer petition until after final action or allowance of the claims provisionally elected.

3.4 THE OBJECTION TO CLAIMS 1 AND 4 IS OVERCOME.

The Action at page 3 objected to claims 1 and 4 allegedly reciting to non-elected subject matter.

Applicants respectfully traverse. However, in order to proceed claims directed to particular aspects of the invention to issuance, Applicants have amended claims 1 and 4 commensurate in scope with the restriction requirement, and as such, should now be allowable based upon the Examiner's remarks on page 3 of the Action.

Applicants now respectfully request that the objection be withdrawn.

3.5 THE REJECTION OF CLAIMS UNDER 35 U. S. C. § 103(A) IS OVERCOME.

The Action at pages 3-8 renews the rejection of claims under 35 U. S. C. § 103(a), allegedly as being obvious over Wraight et al. (WO 00/78341), Thompson et al. (U.S. Patent No. 5,750,390), Pavco et al. and Kido et al.

Applicants again respectfully traverse.

As discussed in Applicants' response to the prior Office Action, these references, neither alone, nor in any combination provide the relevant teaching, suggestion, motivation, or an expectation of success of achieving the claimed invention. In particular, (a) none of the disclosures by Wraight *et al.*, Pavco *et al.*, Thompson *et al.*, and/or Kido *et al.*, provides any guidance about selecting the particular ribozyme target sequences of SEQ ID NO:88 from the entire mRNA sequence that encodes a mammalian IGF-I receptor polypeptide; (b) none of the cited references alone or in combination suggest the particular target sequence within the IGF-1R-encoding mRNA (*i.e.*, SEQ ID NO:88), and none of them provide an expectation of success in constructing a ribozyme that comprises the sequence set forth in SEQ ID NO:100 for the purpose of inactivating such an mRNA sequence; (c) none of these references alone or in combination suggest the *particular ribozyme sequence* of SEQ ID NO:100 would be useful in the

specific cleavage of an mRNA sequence that comprises the specific sequence set forth herein in SEQ ID NO:88.

As such, these references *cannot* render the claimed invention obvious. There is simply insufficient teaching, motivation, suggestion, and expectation of success for using the specific nucleotide sequence (SEQ ID NO:88) within the IGF-1 Receptor-specific mRNA to produce a ribozyme that comprises the sequence of SEQ ID NO:100 that would specifically cleave such an mRNA sequence. Thus, Applicants again respectfully request that the obviousness rejection now be withdrawn, as failing to provide a *prima facie* case of obviousness.

3.6 APPLICANTS AGAIN RENEW THEIR REQUEST FOR REJOINDER OF THE GROUP II INVENTION UPON ALLOWANCE OF THE GROUP I INVENTION

Applicants again note for the record that under the current Statutes, and consistent with the C. F. R., the M. P. E. P, and Technology Center 1600 restriction training materials, if the compositions of the Group I restriction are elected for prosecution, then the subject matter of the Group II and Group III inventions (each directed to processes *for using* the compositions of Group I), is subject to rejoinder upon the allowance of the corresponding composition claims. As such, Applicants again state their affirmative intention to seek rejoinder of the “process for using” claims upon allowance of claims directed to the products claimed in the Group I invention. Referring to the pertinent part of M. P. E. P. § 821.04(b):

“Where claims directed to a product and to a process of making and/or using the product are presented in the same application, applicant may be called upon under 35 U. S. C. § 121 to elect claims to either the product or a process....(T)he claims to the non-elected inventions will be withdrawn from further consideration under 37 C. F. R. § 1.142....(H)owever, if applicant

elects a claim(s) directed to a product which is subsequently found allowable, withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder. All claims directed to a non-elected process invention must depend from or otherwise require all the limitations of an allowable product claim for that process invention to be rejoined. Upon rejoinder of claims directed to a previously non-elected process invention, the restriction requirement between the elected product and rejoined process(es) will be withdrawn.” (emphasis added).

Thus, by constructive election of the products of the Group I invention for initial prosecution on the merits, Applicants again affirmatively state their intention of requesting proper rejoinder of claims directed to processes of using such compositions (*i.e.*, the subject matter of the Group II and Group III inventions) upon allowance of the subject matter of the Group I invention.

3.7 REQUEST FOR CONTINUED EXAMINATION (RCE)

The present RCE is filed within the statutory six month period after the Final Action and is timely in light of the enclosed request for extension of time and fees.

3.8 ENTRY OF AMENDMENTS

The present amendments are entitled to entry after a final rejection as they unambiguously place the pending claims in condition for allowance by adopting the Examiner's suggestions from the Final Action. Applicants are also entitled to entry of the amendment and consideration of the remarks in view of the filing of a Request for Continued Examination.

3.9 RESPONSE TO FINAL ACTION

Applicants incorporate herein by reference all arguments and reasoning presented in the earlier responses on record in the pending matter. It is respectfully submitted that the pending claims are fully enabled by the specification, that all pending claims are definite, and that all claims are free of the cited prior art. Applicants believe that the claims are acceptable under all sections of the Statutes and are now in conditions for ready allowance, and that all of the concerns of the Examiner have been resolved. Applicants respectfully request, therefore, the withdrawal of all rejections and that a Notice of Allowance be issued in the case with all due speed. However, Applicants note for the record their explicit right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing application(s) retaining the priority claim of the present case.

3.10 RENEWED REQUEST FOR EXAMINER INTERVIEW

Applicants again renew their request for an interview with the Examiner *before the issuance of a subsequent Office Action* on the merits to specifically address any particular issues that may remain after consideration of the present paper and entry of the foregoing amendment. Applicants would appreciate the scheduling of such a conference at the Examiner's earliest convenience. In order that Applicants have sufficient time to address any remaining issues following the conclusion of such an interview, Applicants have submitted a 90-day deferral request herewith, pursuant to 37 C. F. R. § 1.103(c), along with a Request for Continuing Examination pursuant to 37 C. F. R. § 1.114. Applicants request that the Office contact the undersigned representative within 30 days' receipt of the present paper to arrange a meeting at a time mutually convenient to the parties.

3.11 CONCLUSION

Applicants believe this to be a complete and timely response to the referenced Action, and that all claims are fully supported and patentable under all sections of the Statutes. As such, a Notice of Allowance and Issue Fee Due is respectfully sought from the Office in response to the present submission. Should the Examiner have any questions, or require anything further, a telephone call to the undersigned Applicants' representative would be welcome.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mark D. Moore", written in a cursive style.

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